OCT 3 0 2001

510(k) Summary of Safety & Effectiveness

K012695

Submitter

Vanguard Medical Concepts, Inc.
5307 Great Oak Drive
Lakeland, FL 33815

Contact

Mr. Mike Sammon, Ph.D.
Director, Research and Development
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Date

August 13, 2001

Device

- Trade Names: Vanguard Reprocessed Arthroscopic Wands
  ⇒ ArthroCare® ArthroWand® Arthroscopic Wands/Electrodes
  ⇒ Mitek® VAPR® Arthroscopic Wands/Electrodes
- Common Name: Arthroscopic wand or electrode
- Classification: 21 CFR 878.4400 – Electrosurgical cutting and coagulation device and accessories – Class II
- Product Code GEI

Predicate Devices

Respective ArthroCare® ArthroWand®, and Mitek® VAPR® legally marketed arthroscopic wands under various 510(k) premarket notifications.

Indications for Use

When coupled with a compatible electrosurgical unit, an arthroscopic wand electrode is intended for resection, ablation and coagulation of soft tissues, and for hemostasis of blood vessels during arthroscopic procedures (of the knee, shoulder, ankle, elbow and wrist) that utilize a conductive irrigant.

Continued on next page

510(k) Summary of Safety & Effectiveness, Continued

Contra-indications

Use of this device is contraindicated for:

- non-arthroscopic surgical procedures,
- arthroscopic procedures during which a conductive irrigant is not used,
- patients for whom arthroscopy is contraindicated, and
- patients with pacemakers or other electronic device implants.

Device Description

The arthroscopic wand electrode is bipolar electrosurgical probe comprised of a shaft with an electrode array at its distal end and a connector at its proximal end for coupling the electrode array to a high frequency power supply. The electrode array has at least one active electrode and at least one return electrode. Return electrodes are electrically insulated from the active ones and are spaced so as not to contact the tissue being treated. The spacing also ensures that the electrical circuit is always completed by a surrounding conductive fluid, and not simply arcing between electrodes. The electrode number and configuration can vary in number and spacing, electrode material, or angle of the distal tip.

In use, the probe is positioned in close proximity to a target site within an electrically conducting liquid, such as an isotonic saline. The conducting liquid provides a current path between the active electrode(s) and the return electrode(s). When radio frequency voltage is applied between the active and return electrodes, high voltage gradients in the distal boundary of the active electrode(s) is sufficiently high to break down the tissue through molecular dissociation or disintegration. The ablative process can be precisely controlled to remove a layer of tissue as thin as a few cells.

Formation of an ionized layer or plasma does not occur when the electrodes are activated with a lower voltage. In this case, electrical current passes through the tissue creating a thermal zone for coagulation of blood vessels and shrinkage of some collagenous tissues of the joints during arthroscopic surgery.

Vanguard receives previously used arthroscopic wands from healthcare facilities; cleans, refurbishes (replaces shaft insulation), inspects, tests, repackages and sterilizes the devices; and returns them to the healthcare facility.

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510(k) Summary of Safety & Effectiveness, Continued

Technological Characteristics	The Vanguard reprocessed arthroscopic wands are essentially identical to the currently marketed OEM wands. No changes are made to the currently marketed device's specifications (except for the insulation material) and they possess the same technological characteristics. Biocompatibility and performance/functional testing demonstrate that the devices are equivalent and continue to be safe and effective for their intended use.
Test Data	Sterilization and packaging validations, functional/performance, nd biocompatibility testing demonstrate that the reprocessed devices perform as intended and are safe and effective.
Conclusion	Based on the information provided herein and the 510(k) "Substantial Equivalence" Decision Making Process Chart, we conclude that the Vanguard reprocessed arthroscopic wands are substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 0 2001

Mike Sammon, Ph.D.
Director, Research and Development
Vanguard Medical Concepts, Inc.
5307 Great Oak Drive
Lakeland, Florida 33815

Re: K012695
Trade/Device Name: Vanguard Reprocessed Arthroscopic Wands
Regulation Number: 878.4400, 888.1100
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Arthroscope
Regulatory Class: II
Product Code: GEI, HRX
Dated: August 8, 2001
Received: August 14, 2001

Dear Dr. Sammon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walker, MD

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K012695

Device Name: Vanguard Reprocessed Arthroscopic Wands

Indications for Use:

When coupled with a compatible electrosurgical unit, an arthroscopic wand electrode is intended for resection, ablation and coagulation of soft tissues, and for hemostasis of blood vessels during arthroscopic procedures (of the knee, shoulder, ankle, elbow and wrist) that utilize a conductive irrigant.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012695